ABSTRACT

Objective To identify, describe and critically appraise the quality of studies of interventions developed to reduce the rate of secondary care utilisation and investigate interventions' impact on patients with type 2 diabetes mellitus (T2DM).

Method Using a systematic approach, five databases were searched between 01/01/1995 and 01/02/2021 (MEDLINE; EMBASE; PsycINFO; CINAHL; and Cochrane database). Inclusion criteria were studies (published in English) in adults with T2DM offered intervention(s) involving medicines/services/educational programmes in any country or setting, with investigated outcomes including the rate of hospital admission/re-admission/A&E visits. Validated tools were used to assess the quality and accuracy of reporting the interventions. A narrative synthesis was used to frame the findings.

Key findings A total of 4670 papers were identified, which yielded a final 53 studies after screening against the inclusion criteria. Identified interventions were: complex interventions (n=21) including at least two interventions (e.g., improving medication adherence and patient education); medication management (n=15); patient education programmes (n=8); lifestyle interventions (n=5); and other interventions (n=4; e.g., dental care). After assessing for quality and effectiveness of interventions, 15 studies remained; seven were medication management interventions, e.g., use of insulin pen, and eight were complex interventions, e.g., pharmaceutical care, telehealth systems. Complex interventions showed significant improvement in clinical outcomes and reduction in secondary care utilisation.

Conclusions This narrative review identified potential elements of an effective complex intervention to reduce healthcare utilisation in patients with T2DM. These results could inform the development of interventions to be tested for feasibility, before piloting to assess for outcomes that improve diabetic care, reduce diabetes-related complications and minimise healthcare utilisation.

Keywords Type 2 diabetes mellitus; hospital admission; hospital re-admission; accident and emergency visit; secondary care utilisation.

INTRODUCTION

Unplanned hospital re-admissions within 30 days of discharge (or generally referred to as emergency re-admission) are rising globally.(1, 2) For example, in the United Kingdom (UK), in 2016-17, there were 529,318 emergency re-admissions reported by 84 hospital Trusts (National Health Service hospitals that provides secondary care services), indicating that over the previous four years the number of re-admissions had risen by 22.8%.(3) A two-fold increase in risk of hospital admission has been demonstrated in patients with diabetes, in comparison to those without diabetes.(4-6) In 2008, around 10% of all UK hospital beds were occupied by patients with diabetes and about 20% of these patients were re-admitted within one year of their last hospital admission.(5) More recent evidence showed that at least one in six hospital beds in the UK were occupied by a patient with diabetes, who tend to be older, have a longer hospital stay and more frequent hospital re-admissions compared to the general population.(7) Similarly, despite their different healthcare systems, the United States (US) Healthcare Cost and Utilisation Project (HCUP) identified diabetes and its associated complications as one of the top ten conditions that contributed to the highest number of all-cause 30-day re-admissions and related costs for Medicaid, for privately insured and uninsured patients (aged 18–64 years).(8)

The high prevalence of diabetes, its complications and suboptimal management were found to have a direct impact on healthcare service utilisation and related costs. For example, the annual report of the US Renal Data System showed that patients with type 2 diabetes mellitus (T2DM) and kidney diseases had an overall Medicare expenditure of $18 billion, accounting for 26.1% of Medicare diabetes expenditure.(9) Figures for the UK published in 2012 suggested that 24,000 people die each year from avoidable causes related to their diabetes, and the National Health Service (NHS) could save £170 million each year through better understanding and management of these patients.(10) The current global emphasis on improving diabetes care and management is therefore understandable, especially in patients with T2DM because of its preventability, in addition to its high prevalence rate and related complications, which can lead to an increased risk of unplanned hospital admissions.(11, 12) A collaborative document from UK diabetes charities, societies and NHS organisations reported that for patients with diabetes admitted to hospital, 52% of those admissions could have been prevented with appropriate proactive care.(13)

Globally, many programmes have been developed with the aim of implementing strategies and action plans to improve care in patients with diabetes and reduce hospital utilisation.(14) For

example, the National Service Framework (NSF) programme for diabetes was established in 2001 with the aim of improving care for patients with diabetes in the UK, improving the quality of services and establishing best practice.(15) The Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND) course for non-insulin users, and the X-PERT course for people with type 1 and 2 diabetes were other examples of national diabetes education courses to improve patient care.(16) In the US, the American Diabetes Association (ADA) has also established different standards intended to provide healthcare professionals, patients, payers, researchers and other interested individuals with the essential components of proper diabetes care. The standards include interventions involving screening, diagnostic, and therapeutic action plans, all of which are believed to improve health outcomes in patients with diabetes. Many of these interventions have also been shown to have financial benefits such as reducing hospital utilisation related cost.(17) The new national diabetes strategies by the Australian government were other international strategies developed to improve diabetes care, similar to those set in the UK and US.(18) The above programmes/strategies contributed to improving glycosylated haemoglobin concentration (HbA1c) levels, reducing hypoglycaemic or hyperglycaemic episodes, reducing hospital utilisation, developing self-confidence in controlling the disease and provide a better quality of life.(16) However, their impact on patients' health was related to their level of engagement. Consequently, there was a national recommendation to address the low uptake rate by choosing the most suitable intervention to achieve the desired outcomes, e.g., increase patient awareness of the positive impact of diabetes courses.(19)

The Economic, Clinical and Humanistic Outcomes (ECHO) model highlights that healthcare interventions need to be planned, conducted and evaluated with acknowledgement of the potential outcome(s) that can be achieved.(20, 21) Excess hospital admissions have increasingly been used as an outcome measure in health service research and as an important quality indicator of health systems and diabetic care, as many admissions due to poor diabetic care and diabetes-related complications are avoidable.(22) Given the prevalence of diabetes and the cost implications of poor management, rates of both hospital admission and Accident and Emergency (A&E) department visits are considered to provide proxy clinical and economic measures of the impact of any intervention intended to improve diabetic care.(23-25) It is inferred that by implementing an effective intervention for reducing hospital re-admissions and A&E visits, both clinical efficacy and cost-avoidance could be achieved. One UK study showed that the triage of suitable patients attending A&E to a diabetes specialist nurse identified those

who could be treated and discharged home without being admitted, saving the NHS around £332 per person. This led to a total cost-saving to that particular hospital Trust of more than £35,000 over 3.5 years.(26) However, evidence is lacking regarding the full range of interventions that have been developed worldwide to reduce the rate of healthcare utilisation in patients with T2DM and which one(s) may be most effective.

Aim of the study

This narrative review aims to identify, describe and critically appraise the quality of studies of interventions internationally developed and delivered to patients with T2DM to reduce the rate of secondary care utilisation and explore interventions' effectiveness in this patient population. The rate of secondary care utilisation considered in this review is the rate of hospital admission/re-admission and A&E visits. The specific research question is: What interventions have been developed to reduce the rate of secondary care utilisation in patients with T2DM and what impact have they had?.

A secondary research question is: What are the component parts of an intervention that are associated with greater impact on the rate of secondary care utilisation in patients with T2DM?.

METHOD

Search strategy

This narrative review followed the systematic approach described in the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA).(27) Reviewing the literature in a systematic way helps researchers to be clear, demonstrate the rigour of their methods, and reduce the potential for bias within a review. This approach also improves the clarity, validity and auditability of the review.(28) Five databases (MEDLINE-In-Process & Other Non-Indexed Citations, EMBASE, PsycINFO, CINAHL, Cochrane database of systematic reviews) were searched between 01/01/1995 and 01/02/2021 for studies in English. Hand searching of reference lists of eligible studies was also conducted. The search strategy and keywords (provided in Supplementary file 1) were discussed by the research team and reviewed by an expert librarian. Inclusion and exclusion criteria (Table 1) were established according to the population, intervention, comparator, outcomes, studies (PICOS) framework, thereby informing the search terms. The Boolean operator OR was used to combine outcome-related terms (e.g., admission*, re-admission*, hospitalisation*, re-hospitalisation*, emergency visit*, emergency re-visit*). These were then combined using AND with T2DM-related terms (e.g., "non-insulin dependent diabetes mellitus", "type II diabetes mellitus"). Studies were first

reviewed for inclusion on the basis of title and abstract and then using full papers. Grey literature were discussed with the research team for inclusion. The literature search, study selection, data extraction, and scoring of data were all conducted by one researcher (SMK). However, to enhance rigour, the data-extraction template and scoring of data were reviewed by another two researchers (CW, PAW). Discrepancies were resolved with a fourth reviewer (HN). Single-data extraction was then performed for all included studies (by SMK) and completed scores and final data extraction was verified (by HN). The research team were consulted in each step to discuss approach, interim findings and review and critically appraise included studies.

Quality assessment

The quality assessment included (1) assessing the quality of the studies, i.e., critically appraising the studies, and (2) assessing the quality and accuracy of reporting the interventions. Included studies were critically appraised using the Critical Appraisals Skills Programme (CASP) checklists.(29) These were applied according to the type of the study, i.e., the CASP Randomised Control Trial (RCT) Checklist, CASP Systematic Review Checklist, and CASP Cohort Study Checklist. No rating scale for this system was specifically developed.(29) However, different reviews have used the CASP total scores to assess the quality of included studies.(30-32) Following the approach used in these studies, each item evaluated was awarded the following qualitative scores: "Yes" (1 point), "No" (0 points), or "Cannot tell" (0 points) to obtain the overall CASP scores.

To assess quality and accuracy of reporting the interventions, the Template for Intervention Description and Replication (TIDieR) checklist was used to assess completeness and detail of reporting.(33) The TIDieR consists of 12 questions related to the intervention, e.g., type of intervention, the reason for providing the intervention, material and process used to deliver the intervention, frequency of delivering the intervention.(33) According to Hoffmann and her colleagues, the checklist contains the minimum recommended items for describing an intervention with the expectation that authors would provide additional information when required for intervention replication.(33) Hoffmann *et al.* emphasised the need to provide sufficient information about the 12 elements and that reviewers should consider marking element(s) as not reported/not sufficiently reported when there is insufficient information about that element.(33) Following the above recommendations (33) and other studies,(34) studies included in this review were scored as 'Yes' for each item that was reported in full, and as 'No' when information about any item was not reported/not sufficiently reported in the primary paper or other related published papers. Then, as considered in a previous study;(34) a summary score

of TIDieR items was used to discriminate between the least and most detailed reports. The scores for the 12 items were calculated to create a summary score from 0 to 12. Lastly, as agreed with the research team, studies with a score < 5 were considered as having poor quality of intervention reporting, between 5 and 8 for fair quality, and > 8 for good quality. However, it should be noted that the TIDieR checklist does not require authors to report modification or fidelity/adherence assessment (items 10, 11 and 12) if none occurred.(35) Therefore, when authors made no mention of modification or fidelity assessment it was assumed that they described interventions without modification or fidelity assessment, and items 10-12 were coded as 'non-applicable'.(35)

For RCT studies, Hoffmann *et al.* recommended using the TIDieR checklist in conjunction with the 25-item Consolidated Standards of Reporting Trials (CONSORT) statement.(33, 36, 37) They recommended using TIDieR checklist as an extension of the fifth item of the CONSORT checklist.(33) Thus, in this review both TIDieR checklist and CONSORT statement were used to evaluate each included RCT study. Adherence to the CONSORT checklist was reported by scoring each item as 1 (if the item was fully reported) or 0 (if not reported/partially reported). Then, following the method used by Montane *et al.*, the quality of RCTs was classified in three categories according to CONSORT score: good (≥ 20 items), fair (between 13 and 19), and poor (≤ 12).(38)

In some studies, e.g., a retrospective data analysis, the use of TIDieR and the CONSORT tool was difficult when assessing the reporting quality of the intervention. In such a case, the Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) guidelines were used. The 18-item SQUIRE criteria help increase the completeness, precision and transparency of important information in the reports of healthcare improvement.(39) Based on the SQUIRE guidelines (39) and SQUIRE explanation and elaboration documents,(40) each item was coded as: 'Yes' where complete information was available/fully reported, 'No' where there was no or incomplete information, or 'not applicable' where the SQUIRE item was not relevant to the study in question. Then, to assess the quality of reporting against the SQUIRE tool, the research team agreed to use the overall score, which was calculated by assigning one point for each fully reported element. Good quality of reporting was considered for a score ≥ 13 (at least 70% of the SQUIRE criteria); fair quality for a score between 7 and 12; poor quality for a score < 7. After assessing the quality of intervention reporting using different tools, the research team excluded studies with poor reporting quality (i.e., insufficient details about the intervention).

The above tools also helped identify the strengths and limitations of the included studies' research methodology, thereby facilitating quality assessment.

Type of interventions

After identifying all relevant interventions, they were screened for similarities and differences. Then, they were inductively classified by the research team according to their nature and number of elements into: complex interventions, medication management interventions, patient education interventions, lifestyle interventions, and other interventions. Complex interventions were those which comprised of at least two of the following activities: lifestyle changes, patient support, education, coordinating the care of participants in their community, monitoring, counselling, improving medication adherence, ward rounds, medication management, assessment, problem-solving and implementation of a telehealth system. Medication management interventions included any changes or additions to patients' medications/regimens, such as using an insulin pen instead of a vial/syringe or having a new oral hypoglycaemic agent (OHA). Patient education interventions included studies on diabetes self-management educational programmes conducted to improve patient's clinical outcomes and reduce rates of secondary care utilisation. Lifestyle interventions referred to any intervention that included exercise, diet, goal-setting, and other lifestyle changes such as smoking cessation.

Measures of the intervention effect

The research team had frequent meetings and group exercises to review and discuss all strengths and weaknesses of the included interventions. Then, they set specific criteria to evaluate the effect of the interventions in reducing the rate of secondary care utilisation in patients with T2DM. An intervention was considered to be effective if it had:

- A statistically significant reduction in hospital admission/re-admission rates or A&E visits.
- A sustainable effect during the follow-up period. Studies were excluded if the effect on admission rate did not last after cessation of the intervention or after one year follow-up, which the authors reported as a limitation for the studied intervention.
- No or low rate of patient drop-out (< 20%), as this review aims to identify the most effective intervention with a sustainable effect and suitable to all patients with T2DM. Previous studies found that ≥ 20% of patient drop-out is considered a high rate that may bias the result and limits its generalisability.(41-43)

- No risk of bias (as reported by the study authors), which is used to inform the synthesis of the studies' findings and integrated into the overall assessment of the certainty of the body of evidence.
- The intervention was not provided to a specific population, as it would be difficult to generalise the result to the wider group of patients with T2DM.

RESULTS

Results of Cochrane Database search

The Cochrane database search resulted in only four systematic reviews of interventions developed to reduce the rate of secondary care utilisation.(44-47) Two systematic reviews focused on the use of telehealth communication systems and mobile phone messaging applications.(44, 45) The systematic reviews assessed three main outcomes: mortality, hospital admission and disease-specific quality of life in different chronic diseases. However, the evaluation of hospital admission outcome was not in patients with T2DM.(44, 45) The third systematic review discussed the impact of diabetes specialist nurses on patients' conditions and outcomes. Among the included studies (n = 6), only two evaluated the admission rate; one was on paediatric patients and the other one did not specify type of diabetes, i.e., type 1 or 2.(46) The last systematic review evaluated the impact of shared care health services between primary and speciality care on the management of chronic diseases.(47) In this review, only nine studies considered rate of hospital admission as an outcome, of which only one study included patients with diabetes, but the results of hospital admission rate did not differentiate between patients with type 1 and type 2 diabetes mellitus.(48) Thus, it was excluded. In summary, none of the systematic reviews met the inclusion criteria for this narrative review.

Results of the other databases

For the remaining databases (MEDLINE; EMBASE; PsycINFO; CINAHL), a total of 4670 papers were identified, which following screening (titles and abstract), resulted in 177 relevant papers. After reviewing full papers, 53 met the inclusion criteria. Figure 1 gives an overview of screening process using the PRISMA flow chart.

Figure 1. PRISMA flow chart of the narrative review results.

The identified interventions (n=53) were complex interventions (n=21), medication management interventions (n=15), patient education programmes (n=8), lifestyle interventions (n=5), and other interventions (n=4) such as dental care support. No relevant qualitative studies

were identified from this review; there was a lack of contextual information gathered from the literature.

1. Complex interventions

Studies on complex interventions had different designs, of which some were conducted as RCTs (n=10),(49-58) pre- and post- studies (n=5),(43, 59-62) or cohort studies (n=6).(63-68) The majority of these studies were conducted in hospital settings (n=7),(51, 54, 56, 59, 61, 65, 66) primary care centres (n=5),(43, 49, 50, 55, 63) or community-based settings (n=5),(52, 53, 60, 62, 68) while other studies (n=4) were conducted in both hospital and community-based settings.(57, 58, 64, 67)

A total of 17 studies measured the level of glycosylated haemoglobin concentration (HbA1c) as the clinical outcome, for which most of the studies reported a significant reduction (n=10).(51, 55-57, 59-61, 64, 66, 68) This significant reduction in the level of HbA1c was observed in all patient populations, including those ≥ 65 years old.(51, 56, 61) In contrast, there was a conflict in the rate of secondary care utilisation, especially as not all of the studies were powered to detect a difference in the admission rate/A&E visits because it was a secondary outcome.(43, 49, 50, 52, 60) In addition, none of the identified studies with complex interventions (n=21) reported the diabetes severity or its progression states. All studies, except one,(56) were assessed as having good quality of intervention reporting. However, not all of the high-quality studies demonstrated a significant influence on the rate of secondary care utilisation.(43, 49-52, 55, 58, 60, 62, 65, 66) Only nine studies showed a significant reduction in the rate of secondary care utilisation.(53, 54, 57, 59, 61, 63, 64, 67, 68) In most of these studies, authors did not define if these were diabetes-related or non-diabetes-related admissions,(53, 57, 59, 61, 64, 68) while the reduction in diabetes-related admission was only reported in three studies.(54, 63, 67)

2. Medication management interventions

These interventions included changing the insulin delivery device (n=6),(69-74) using long-acting insulin (LAI) (n=3),(75-77) changing the route of insulin administration (n=1),(78) the use of insulin versus other antidiabetic medications, such as exenatide, thiazolidinediones and glucagon-like peptide (GLP-1) (n=3),(79-81) and a comparison between different OHAs (n=2); thiazolidinediones therapy versus other OHAs (82) and dipeptidyl peptidase-4 inhibitors (DPP4-Is) therapy versus sulfonylurea.(83)

Studies using LAI demonstrated fewer hospital admissions and re-admissions compared with those on other insulin therapy (e.g., rapid-acting insulin (RAI) and pre-mixed insulin),(76) but this difference was not significant when compared with those taking OHAs.(75) Both studies included all adult patients with T2DM and had the same follow-up period, i.e., patients were followed over the 1-year period following initiation of insulin therapy. However, studies were conducted in different settings/countries, in which some regional and cultural variations may impact on hospital admissions/re-admissions rate.

Studies analysing different national large databases in the US showed that using an insulin pen in adult patients with T2DM was better than using a vial/syringe in reducing the rate of secondary care utilisation.(69-73) However, as these studies were conducted retrospectively there was a lack of knowledge of patients' clinical history and medical condition. In addition, there may be uncontrolled/unmeasured variables. For example, Lee *et al.*, reported that they did not have access to some important data such as race and income which may have highlighted potential differences between the study groups.(72) Other retrospective cohort studies had also reported having uncontrolled variables (e.g., HbA1c, medication adherence, diabetes severity), which may indicate the presence of selection bias.(75, 79, 80, 83) These uncontrolled factors were found to have an important impact on patients' clinical, economic, and healthcare utilisation outcomes. Therefore, for studies with uncontrolled variables, no strong evidence of the effect of certain interventions could be drawn due to the study design used. Other potential risks of bias were reported in some studies when collecting data from different databases.(80, 83) The risk of coding errors in patient data, e.g., entering wrong code for hypoglycaemic events, could lead to less robust results subject to a declaration bias.(80, 83) Therefore, future researchers should understand and address the different types of bias when designing or evaluating any intervention to have high-quality evidence of the intervention's impact on the rate of secondary care utilisation.

3. Patient education interventions

Most of the studies with educational programmes compared the outcomes pre- and post-intervention for patients with T2DM.(42, 84-86) In addition, the majority of the patients were recruited from either the community (42, 84, 85, 87, 88) or from the hospitals.(41, 86, 89) Studies conducted between six months and three years had a non-significant reduction in the rate of hospital admission and A&E visit,(42, 84, 86-88) while those undertaken for a longer period (> 4 years) had a significant difference between the study groups.(41, 85) Therefore, it was concluded that educational interventions required a longer timeframe to show the

significant effect on the rate of hospital admission. However, such intervention had a high drop-out rate (≥ 25%), especially when the programme was conducted for an extended period.(41, 42) There were also conflicting results related to reduction in the HbA1c. Studies with extended follow-up periods (> 4 years) showed the level had reduced significantly.(41, 85) However, in studies with 6 to 12 month follow-up periods, some demonstrated a significant reduction,(42, 88) while others did not have a strong influence on the level of HbA1c.(86, 87)

4. Lifestyle interventions

Five studies with lifestyle interventions to improve patient care and secondary care utilisation were identified. Four studies were RCTs (90-93) and one had a systematic review and meta-analysis study design.(94) For the RCTs, two studies primarily evaluated the effect of intensive lifestyle intervention on the use and cost of healthcare services.(90, 92) The interventions consisted mainly of goal-setting for calorie restriction, dietary fat restriction, improved physical activity, frequent on-site treatment sessions, and consultation over the phone, mail, or e-mail.(90, 92) The study by Espeland *et al.* found a significant reduction in the all-cause hospital admissions. However, most of the admissions (62%) were non-diabetes related.(90) In contrast, Huckfeldt *et al.* did not find any significant reduction in all-cause hospital admissions and A&E visits.(92) The third RCT evaluated the cost reduction of implementing lifestyle interventions (e.g., education sessions, goal-setting, patient support) in obese patients. Even though there was a significant reduction in the number of hospital admissions, the authors did not define if these were diabetes-related or non-diabetes-related admissions.(91) The last RCT on lifestyle interventions compared group care in a diabetes outpatient clinic with individual care using different measures including the number or hospital re-admission.(93) The study did not find a significant impact of the studied intervention on hospital re-admission rate.

The systematic review explored the effectiveness of lay-led, group-based self-management interventions to improve HbA1c level, self-efficacy and A&E visit rates.(94) Of the 16 included RCTs, only four studies measured the number of A&E visits in the past six months.(87, 95-97) The meta-analysis of these studies revealed the statistically significant effect of the lay-led, group-based self-management interventions on the number of A&E visits.(94) However, studies varied in their risk of bias. The reported high risk of bias among the studies in the domains of detection bias, performance bias, and attrition bias would diminish the quality of evidence shown through the meta-analysis.(94) Overall, studies on lifestyle interventions demonstrated conflicting findings regarding the impact on secondary care utilisation.

5. Other interventions

Studies on other interventions included the impact of Pay-for-Performance (P4P) programme,(98) concordance with guidelines,(99) impact of an oral enteral nutrition with a hypercaloric diabetes-specific formula,(100) and dental care intervention.(101) Of these studies, only three showed significant reduction in the rate of secondary care utilisation.(98, 100, 101) However, the study on the effect of dental care intervention did not have a clear explanation for the potential cause-and-effect mechanism between regular dental care and the significant reduction in the rate of hospital admission and A&E visit.(101)

CASP appraisal results

The CASP quality assessment of included studies is outlined in Supplementary file 2. The results showed that the average CASP score for RCTs was 7/11, with the lowest score of 3/11 and the highest score being 9/11 (SD ± 1.56). While for cohort studies, the average CASP score was 8/12, with the lowest score of 3/12 and the highest score of 12/12 (SD ± 2.32). According to Al-Dirini *et al.*, the average CASP score for all the studies indicates an acceptable level of relevance and quality.(32) In this review, most of the RCTs (n=12) and cohort studies (n=17) had an acceptable level of relevance and quality.

The CASP quality assessment also demonstrated that most of the included RCTs (n=15) did not have a positive value for the last item of the CASP RCT checklist (the value of the studied intervention compared to the existing interventions). This item concerns the resources needed to introduce the interventions (e.g., time, money, skills development or training needs) and the ability to disinvest resources of existing interventions and re-invest them in the new intervention. However, most included studies either did not provide sufficient information on the resources used to implement/deliver the interventions or information about the contextual factors related to individual needs (i.e., potential barriers and facilitators) to implementing the new interventions into the current practice.

Effective interventions

After assessing for quality and considering measures of the intervention effect (defined by the research team such as statistical significance of the results, patient drop-out rate), 15 studies remained; seven were medication management interventions (69-73, 79, 83) and eight were complex interventions.(51, 53, 57, 59, 61, 63, 64, 67) Figure 2 provides an evaluation flow chart of these interventions and the basis of exclusion.

Figure 2. Intervention(s) evaluation flow chart.

Medication management interventions

Medication management interventions were found to have a significant effect on patients' clinical outcomes and the use of healthcare services. For example, there is fair to good evidence for the impact of using insulin pens in patients with T2DM on reducing secondary care utilisation compared to those using vial/syringe. In addition, the evidence identified patients using insulin via vial/syringe are high-risk patients who had poor medication adherence that could lead to frequent admissions.(69-73) Other good evidence related to using different diabetic medications (exenatide therapy, DPP4-I) should be considered according to the patients' individual needs.(79, 83) Details of these interventions are shown in Table 2.

Complex interventions

The included studies varied in their design, some were RCTs,(51, 53, 57) while the others were either pre- and post- study,(59, 61) or cohort study design.(63, 64, 67) There was also a variation in study duration. Three studies were conducted between 3-6 months,(51, 59, 61) while others were conducted over a longer duration (≥ 1 year).(53, 57, 63, 64, 67) Moreover, the studies varied in their nature, of which some evaluated the role of intensive pharmaceutical care (n=2),(51, 59) the effect of intensive nurse care management (n=2),(53, 61) the effect of using telehealth systems (n=3),(57, 63, 64) and the impact of an integrated model of care (n=1).(67) Details of these interventions are provided in Table 3.

In general, the identified effective complex interventions had different components (different types of care). Studies of the same type of intervention, e.g., intensive pharmaceutical care, also varied in their intervention components.(51, 59) The follow-up care was the common intervention component delivered to the patients in all included studies (n=8).(51, 53, 57, 59, 61, 63, 64, 67) Examples of follow-up care include medication review, follow-up visits/phone calls, insulin dose adjustment, and monitoring patient's blood glucose level. The second commonly delivered intervention component to reduce secondary care utilisation in patients with T2DM was patient counselling and education (n=7).(51, 53, 57, 59, 61, 63, 64) This was followed by coordination of care (n=4) such as referring patients to diabetes educators or dietitians,(51, 59, 63, 67) and communication between different healthcare providers or between patients (n=4), e.g., making recommendations to physicians and patients online forum.(51, 53, 57, 59)

Other less delivered intervention components were: (1) cognitive–behavioural care (n=2) (51, 61) which refers to any psychosocial treatment that aims to improve mental health and reduce

distressing emotional experiences or problematic behaviour by changing how the individual assesses and interprets their experiences,(102) (2) patient-centred care (n=2),(53, 57) i.e., providing individualised, tailored care using evidence-based clinical practice and based on patient preferences, needs and values, and (3) transfer of care (n=1), i.e., the process of reviewing and discharging patients back to their referring general practitioner once their clinical targets are achieved or if no further improvement can be achieved.(67)

DISCUSSION

This narrative review has critiqued the evidence on interventions developed to reduce secondary care utilisation in patients with T2DM. Five types of interventions were identified: complex intervention, medication management, patient education programmes, lifestyle support, and other interventions such as the impact of an oral enteral nutrition intervention. This review has provided a detailed description of the interventions' components and outcomes. It found that both medication management interventions (e.g., the use of insulin pen) and complex interventions (e.g., intensive pharmaceutical care) were effective in reducing the rate of secondary care utilisation in patients with T2DM. However, the use of medication management interventions depends upon the individual's preference and on case-by-case needs. In contrast, different components of complex interventions effectively reduced secondary care utilisation for patients with T2DM. The review also provided evidence for the acceptable relevance and quality of most included studies.

The principal strength of this review is that it has attempted to identify and analyse all interventions developed or provided to patients with T2DM to reduce their secondary care utilisation. To our knowledge, the focus of this narrative review was not considered in any previous studies. Most other reviews have focused on one intervention, e.g., telehealth communication system, and evaluated its impact on secondary care utilisation.(44-46) In other reviews, the authors did not differentiate between the intervention's impact on hospital admission rate in patients with type 1 and type 2 diabetes.(48) Another strength of this review is that validated tools were used to assess the completeness of reporting the intervention and the study, such as the TIDieR and CONSORT checklists, which provide the reader with a comprehensive understanding of the intervention elements and study design for future evaluation and replication of these interventions. However, this narrative review still has some limitations. Firstly, we only included studies in the English language. Secondly, one reviewer undertook the study selection and data extraction. Thirdly, we did not include names of specific

interventions in the search strategy (e.g., intensive pharmaceutical care or integrated model of care), which could give the search more sensitivity to identify further eligible studies. Finally, the intervention effect measures (e.g., intervention having a sustainable effect or low rate of patients' drop-out) were chosen based on discussion by the research team. Therefore, future researchers could consider other factors in evaluating the intervention effect on the rate of secondary care utilisation in patients with T2DM.

This review had identified that interventions with behavioural change components (education programmes and lifestyle interventions) produced a significant reduction in the rate of secondary care utilisation when they had an extended follow-up period exceeding four years.(41, 62, 85, 91) While those with a short follow-up period (<4 years) did not find significant findings, which is also related to recent two RCTs estimating the association between behavioural change interventions and healthcare utilisation and spending.(103, 104) Both studies were conducted for less than two years, included all individuals regardless of their medical condition, and considered intervention components that are similar to the behavioural change interventions identified in our review.(103, 104) Another case-control study evaluating the effect of an 8-week lifestyle intervention program for adults with metabolic syndrome also showed a non-significant reduction in hospital admissions. The only difference between study groups was related to the A&E visits.(105) The variation in the effect of behavioural change interventions could be attributed to the duration of the follow-up period (as discussed before), study design, or interventions content and delivery. However, such interventions might not be suitable for resource limitations or when service designers/implementers want to measure the intervention effect within a specific timeframe. In addition, they have a high drop-out rate;(41, 42) thus, caution should be considered when replicating these interventions in different groups, settings and contexts. Researchers are recommended to apply theoretical tools to identify and address target behaviour changes.(106) The Behaviour Change Wheel (BCW) model by Michie *et al.* is one of the suggested models used to provide sufficient understanding of patients' behaviour before characterising and designing behaviour change interventions which would also help evaluate the intervention outcomes.(106)

The different components of complex interventions identified from this review were related to the significant reduction in the healthcare utilisation. It was found that interventions including most of these components had a significant improvement in HbA1c and lower rate of secondary care utilisation of wider groups of patients with T2DM, i.e., the more clinical input leads to better outcomes.(51, 57, 59, 61) However, given the heterogeneous nature of the complex

interventions, it is not possible to identify which component(s) are most useful/effective. To address this complexity, researchers are encouraged to adopt a systematic approach to the design and evaluation of complex interventions as outlined by the British Medical Research Council (MRC).(107) A logic model is recommended at the outset to clearly articulate the intervention, the underlying assumptions and anticipated benefits in the form of outcomes and impact. The MRC describe the need to undertake a process evaluation alongside an outcome evaluation.(108, 109) The goal of the process evaluation is to explain the pathways linking the intervention and its underlying causal assumptions to the outcomes produced. To achieve this, the implementation process, mechanisms of impact and context should be considered.(108) Unfortunately, there was an absence of intervention process evaluations for this review. This means deductions about intervention effectiveness are limited to degrees of success or failure, but with minimal possibility to understand the attributable mechanisms and/or intervention components. A recent process evaluation of a complex intervention (the transfer of care service from hospital to community pharmacy) indicated that identifying contextual factors related to the implementation process and fidelity of the intervention would facilitate short and long-term outcomes evaluation of the intervention, e.g., evaluation of clinical outcomes and secondary care utilisation.(110) The study identified different barriers to the delivery and use of the transfer of care intervention which caused significant issues with the implementation process and resulted in suboptimal intervention fidelity. These factors included the lack of staff training, staff and patients awareness of the intervention, clarity on the intervention specification, monitoring, information and feedback from community pharmacies about patient's condition and outcomes. The authors highlighted that effective interventions should have high implementation fidelity to achieve successful outcomes. Therefore, they illustrated components of the intervention that enhance the potential for diffusion and wider adoption. For example, they discussed the need for a clear specification that facilitates the standardisation of the quality and content of intervention delivery and operation. Providing ongoing training and awareness to intervention providers was also recommended to embed the intervention into practice.(110) Moreover, previous studies found that having a specific plan to enhance and monitor intervention fidelity will enable investigators to draw more accurate conclusions regarding the validity and effectiveness of the interventions.(106, 111) It also will guide future intervention designers/evaluators in testing and selecting the most appropriate components to produce the required behaviour and outcomes.(111)

There is also growing recognition and appreciation for the adoption of realist methodologies to evaluate complex interventions. Conventional RCTs help understand the effectiveness of interventions in their highly experimental, controlled conditions with little information provided on how to replicate the intervention in other contexts and settings or whether trial outcomes will be reproduced.(109) In contrast, the realist approach helps evaluators understand what is happening in practice, how common problems occur and how they can be overcome, and how new practices delivered within the intervention can become normal practice leading to better outcomes. Realism seeks to understand not only whether an intervention works, but what it is about it that works, for whom, in what circumstances and why.(112) The multiple moving parts of a complex intervention would benefit from this theoretical lens to disentangle the casual mechanisms and dynamics at play as the intervention negotiates within the context it is being delivered.

This review showed that some effective interventions could be broadly applicable to patients with T2DM to reduce their secondary care utilisation. However, the lack of knowledge of contextual information and resources needed to implement/deliver these interventions is limiting the generalizability of the findings of this review and the interventions replication in other settings and contexts. In addition, sustaining the impact of some delivered interventions on secondary care utilisation in patients with T2DM is still not well understood due to the lack of follow-up.

CONCLUSION

This narrative review identified different interventions that can be implemented to reduce the rate of secondary care utilisation in patients with T2DM. It also identified some complex interventions with different components that proved to be effective in reducing secondary care utilisation of patients with T2DM. The common delivered components of complex interventions to reduce secondary care utilisation were providing follow-up care, counselling/education, coordination of care and communication between different health care providers. However, given the heterogeneous nature of complex interventions, it has not been possible to draw definitive deductions about intervention components contributing the most effect. Future intervention designers and evaluators are recommended to plan a systematic and comprehensive approach to undertake process evaluations alongside outcome evaluations to better understand the ‘why’ of intervention success or failure. This would improve the generalizability and replicability of the interventions in other settings and contexts. Realist

methodologies offer further opportunity for evaluators to understand how interventions work (or not), for whom and in which circumstances, thereby providing significant information to contextualise outcomes but also prove to be the most useful to inform future policy and practice.

Declarations

Conflict of interest

The Authors declare that they have no conflicts of interest to disclose.

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890 **Table 1. Inclusion and exclusion criteria.**

Population	All adults with T2DM who were admitted to hospital or not, were included if they received any intervention to reduce their rate of hospital admission/re-admission and A&E department visits. The search focuses on adults with T2DM only, however, studies on both type 1 and 2 diabetes which presented the results separately for both types were also included. Studies with all age groups were also considered only if they had reported adult results separately. Exclusion criteria were paediatric patients, pregnant/breastfeeding women, gestational diabetes, type 1 diabetes, and non-specified type of diabetes.
Interventions	The included articles reported on intervention(s) involving medicine(s), service(s), educational programme(s) delivered in any country and setting, and including an intended outcome of reducing the rate of hospital admission/re-admission and/or A&E visits in patients with T2DM. Studies with insufficient details about the interventions (had a low quality of reporting the intervention) were excluded.
Outcomes	The main outcome was the rate of hospital admission/re-admission and/or A&E visits in patients with T2DM. The rate of hospitalisation or re-hospitalisation was also considered if it was defined as the frequency of patients being admitted. Excluded outcome measures included the length of hospital stay, the risk of admission/re-admission or the risk of hospitalisation/re-hospitalisation, cardiovascular risk factors or outcomes and studies evaluating drug safety and/or efficacy. Studies were also excluded if authors did not report sufficient details on secondary care utilisation.
Studies	Studies published between 01/01/1995 and 01/02/2021 in any country were included. All study designs were considered, e.g., RCTs, non-randomised controlled trials, cohort studies, pre- and post- studies, observational studies and systematic reviews. Excluded papers included those not in English, ongoing trials, study protocols, dissertations, organization papers, books, meeting notes, guidelines, and those with no full text available.

891 ***Abbreviations:*** *T2DM, type 2 diabetes mellitus; A&E, accident and emergency; RCTs, randomised control trials.*

892 **Table 2. Studies on medication management intervention.**

Author	Sample size	Design/ duration	Setting	Intervention name	Intervention components	Control group	Outcomes of interest	Quality of reporting
Ayyagari *et al.* 2015 (69)	13,428 adult patients	Retro-spective data analysis 12 months	Data obtained from a national database of > 45 private and government-sponsored health plans (covering hospital & community-based settings) in the United states	Insulin pen	The use of insulin pen in patients who had at least one claim for basal insulin (glargine, detemir, or Neutral Prot-amine Hagedorn insulin)	Insulin via a vial	The significant reduction in the results was in favour of insulin-pen-users. **Reduction in HbA1c level** – S (in pen users) **Reduction in the rate of hospital admission** – S (in pen users)	Fair*
Xie *et al.* 2014 (70)	1,308 adult patients	Retro-spective cohort design 12 months	Data obtained from a research database which includes claims from all settings in Minnesota, United states	Insulin pen	The use of insulin glargine via a disposable pen	Insulin via a vial	The significant reduction in the results was in favour of insulin-pen-users. **Reduction in HbA1c level** – S **Reduction in secondary care utilisation:** • Diabetes-related hospital admissions – S • All-cause hospital admissions – NS • All-cause & diabetes-related A&E visits – NS • A&E and inpatient/A&E-related Hypoglycaemic events – S	Fair*

893 ***Abbreviations:*** *HbA1c, glycosylated haemoglobin concentration; S, significant difference between the study groups; NS, non-significant difference; A&E, accident and emergency.*
894 **Assessed using SQUIRE criteria (poor < 7, fair between 7 and 12, Good ≥ 13 scores).*

Table 2. Studies on medication management intervention (Cont.).

Author	Sample size	Design/ duration	Setting	Intervention name	Intervention components	Control group	Outcomes of interest	Quality of reporting
Davis *et al.* 2011 (71)	3,842 adult patients	Retro-spective cohort design 12 months	Data obtained from a national database of 46 types of managed care plans (covering all settings) in the United states	Insulin pen	The use of insulin glargine via a disposable pen	Insulin via a vial	The significant reduction in the results was in favour of insulin-pen-users. **Reduction in HbA1c level** – S **Reduction in secondary care utilisation:** • All-cause hospital admissions and A&E visits – NS • Diabetes-related hospital admissions – S • Diabetes-related A&E visits – NS	Good*
Lee *et al.* 2006 (72)	1,156 adult patients	Retro-spective cohort design > 4 years	Data obtained from an integrated medical and pharmacy claims database covering 57 managed care health plans from all settings in the United states	Insulin pen	The use of an insulin analogue pen containing insulin aspart (NovoLog® FlexPen) or biphasic insulin aspart protamine (NovoLog ® Mix 70/30 FlexPen) for the first time	Insulin via a vial	The significant reduction in the results was in favour of insulin-pen-users. **Reduction in secondary care utilisation:** • Hypoglycaemic-related admissions – NS • Hypoglycaemic A&E visits – S	Good*

Abbreviations: *HbA1c, glycosylated haemoglobin concentration; S, significant difference between the study groups; A&E, accident and emergency; NS, non-significant difference.*
**Assessed using SQUIRE criteria (poor < 7, fair between 7 and 12, Good ≥ 13 scores).*

Table 2. Studies on medication management intervention (Cont.).

Author	Sample size	Design/ duration	Setting	Intervention name	Intervention components	Control group	Outcomes of interest	Quality of reporting
Eby *et al.* 2013 (73)	8,374 adult patients	Retro-spective cohort design > 4 years	Data obtained from a database of retrospective claims covering hospital & community-based settings in the United states	Insulin pen	Administration of mealtime insulin (insulin aspart, insulin glulisine, insulin lispro, insulin lispro mix 75/25 and 50/50) via disposable pens	Insulin via a vial	The significant reduction in the results was in favour of insulin-pen-users. **Reduction in secondary care utilisation:** • All-cause hospital admissions – S • Diabetes-related admissions – S • Diabetes-related A&E visits – S	Fair*
Pawaskar *et al.* 2011 (79)	10,074 Adult patients	Retro-spective cohort design 26 months	Data obtained from a large claims database for over 30 million patients from both hospital & community-based settings in the United states	Exenatide therapy	The use of exenatide therapy twice a day	Glargine therapy	The significant reduction in the results was in favour of the exenatide group. **Reduction in secondary care utilisation:** • All-cause hospital admissions – S • Admissions due to diabetes macrovascular complications – S • Admissions due to microvascular complications – NS • Rate of A&E visit – NS	Good*
Detournay *et al.* 2015 (83)	18,611 adult patients	Retro-spective cohort design 3 years	Data obtained from a database containing records from both hospital & community-based settings in France	DPP4-I therapy	Regimens containing DPP4-I, excluding treatment with IS (sulfonylureas or glinides), insulin, or any incretin therapy.	IS excluding treatment with insulin & any incretin therapy	The significant reduction in the results was in favour of the DPP4-I group. • Reduction in hypoglycaemic-related hospital admissions – S • Reduction in hypoglycaemic-related A&E visits – S	Good*

Abbreviations: *S, significant difference between the study groups; A&E, accident and emergency; NS, non-significant difference; DPP4-I, dipeptidyl peptidase-4 inhibitor; IS, insulin secretagogues.*

**Assessed using SQUIRE criteria (poor < 7, fair between 7 and 12, Good ≥ 13 scores).*

Table 3. Studies on complex intervention.

Author	Sample size	Design/ duration	Setting	Intervention name	Intervention components	Control group	Outcomes of interest	Quality of reporting
Chen *et al.* 2016 (51)	100 patients aged ≥65 years	RCT 6 months	A 421-bed district hospital in Taiwan (Hospital-based setting)	Intensive pharma-ceutical care provided by a certified diabetes educator pharmacist	Counselling/education Communication (making recommendations to physicians) Coordination of care (referral of patients to other diabetes care team members) Cognitive–behavioural care (cognition evaluation and depression screening) Follow-up care (confirming medication adherence to pill-box use and insulin injection, medication review, follow-up visits)	Usual care provided by the diabetes care team which included physicians, certified diabetes educator nurses, and dietitians (without pharmacist)	The significant reduction in HbA1c level was in favour of the intervention group. **Primary outcome:** Reduction in HbA1c level – S **Secondary outcomes:** • Reduction in the rate of hospital admission – NS • Hospital admission due to hypoglycemia – No admissions reported in the intervention group	Good*
Xin *et al.* 2014 (59)	Pre-420, post-429 adult patients	Pre- & post-study design 6 months	A 1200-bed teaching hospital in China (Hospital-based setting)	Intensive pharma-ceutical care provided by a clinical pharmacist	Counselling/education Communication (reviewing drug costs, making medication and laboratory recommendations) Coordination of care (making ward rounds with physicians) Follow-up care (reviewing lab results, checking previous admissions/ADR, medication review, goal-setting)	Usual care without pharmacist involvement	The significant reduction in the results was obtained following the intervention delivery. **Primary outcome:** Reduction in HbA1c level – S **Secondary outcomes:** Reduction in the rate of hospital admission – S	Good**

Abbreviations: *RCT, randomised control trial; HbA1c, glycosylated haemoglobin concentration; S, significant difference between the study groups; NS, non-significant difference; ADR, adverse drug reaction.*

**Assessed using CONSORT score (poor ≤ 12, fair between 13 and 19, good ≥ 20 scores).*

***Assessed using TIDieR checklist (poor < 5, fair between 5 and 8, good > 8 scores).*

Table 3. Studies on complex intervention (Cont.).

Author	Sample size	Design/ duration	Setting	Intervention name	Intervention components	Control group	Outcomes of interest	Quality of reporting
Gary *et al.* 2009 (53)	542 adult patients	RCT 3 years	An urban managed care organisation in the United states (Community -based setting)	Intensive nurse care management intervention provided by a nurse case manager in the clinic and a community health worker in the home	Counselling/education Patient-centred care (individualised, culturally tailored care using evidence-based clinical algorithms) Communication (send feedback to primary care providers) Follow-up care (mailings and phone calls)	Usual care (follow-up care) consisting of mailings and phone calls follow-up by a community health worker	The significant reduction in the A&E visit was in favour of the intervention group. **Primary outcome:** Reduction in the rate of A&E visit – S **Secondary outcomes:** • Reduction in the rate of hospital admission – NS • Reduction in HbA1c level – NS	Good*
Chan *et al.* 2006 (61)	150 old patients	Quasi-experi-mental/ Pre- & post-study design 3 months	An acute hospital in Hong Kong (Hospital-based setting)	Intensive nurse care management intervention provided by trained diabetes nurses	Counselling/education Cognitive–behavioural care (use behavioural techniques to improve patient's self-care of chronic illness) Follow-up care (review blood glucose home-monitoring, medication and insulin dose adjustment, monitor quality/ outcome of care, improve medication adherence, and phone call follow-ups)	Usual care (follow-up care) including general medication adjustment, review blood glucose home-monitoring, blood pressure, and body weight	The significant reduction in the results was obtained following the intervention delivery. • Reduction in HbA1c level between groups and in nurse clinic group – S • Reduction in composite end-point of hospital admissions and A&E visits (between groups) – S	Good**

Abbreviations: *RCT, randomised control trial; A&E, accident and emergency; S, significant difference between the study groups; NS, non-significant difference; HbA1c, glycosylated haemoglobin concentration.*

**Assessed using CONSORT score (poor ≤ 12, fair between 13 and 19, good ≥ 20 scores).*

***Assessed using TIDieR checklist (poor < 5, fair between 5 and 8, good > 8 scores).*

Table 3. Studies on complex intervention (Cont.).

Author	Sample size	Design/ duration	Setting	Intervention name	Intervention components	Control group	Outcomes of interest	Quality of reporting
Chen *et al.* 2011 (64)	64 adult patients	Cohort study 12 months	General hospital diabetes centre in Taiwan (Hospital & community -based settings)	The use of telehealth system intervention provided by diabetes educators	Counselling/education (one-hour phone call instruction on the use of telehealth system, phone calls for specific barrier education) Follow-up care (regular monitoring of patient's blood glucose levels, phone calls for confidence establishment, insulin dose adjustment, and outpatient clinic visits)	Intensive diabetes management care including outpatient clinic visits and phone calls follow-up (follow-up care)	The significant reduction in the results was in favour of the intervention group. **Reduction in HbA1c level:** • For the control group – NS • For the telehealth group – S **Between groups:** • Reduction in the rate of hospital admission – S • Reduction in the rate of A&E visit – NS	Good*
Barnett *et al.* 2006 (63)	800 old patients	Cohort study 2 years	Four medical centres in the United states (Primary care setting)	The use of telehealth system intervention provided by registered nurses or advanced registered nurse practitioners	Counselling/education Coordination of care (making an appointment with the patient's physician) Follow-up care (phone calls follow-up, monitoring and assessing patients' health and medications based on their answers to specific daily questions, and reminding patients about their appointments)	Patients not using care coordination home telehealth system	The significant reduction in the results was in favour of the intervention group. **Difference from baseline to the 24-month follow-up:** All-cause and diabetes-related admission rates – S **Difference between groups:** • All-cause hospital admissions – S • Diabetes-related hospital admissions – NS • All-cause & diabetes-related A&E visits – S	Good*

Abbreviations: *HbA1c, glycosylated haemoglobin concentration; NS, non-significant difference; S, significant difference between the study groups; A&E, accident and emergency.*
**Assessed using TIDieR checklist (poor < 5, fair between 5 and 8, good > 8 scores).*

Table 3. Studies on complex intervention (Cont.).

Author	Sample size	Design/ duration	Setting	Intervention name	Intervention components	Control group	Outcomes of interest	Quality of reporting
Wang *et al.* 2019 (57)	120 patients	RCT 12 months	Patients admitted to the department of endocrinology of one hospital in China (Hospital & community -based settings)	The use of telehealth system intervention provided by multi-disciplinary team	Counselling/education (the application provided information on diabetes, diet, sports and medication) Patient-centred care (patients received a one-to-one interaction with physicians) Communication (online forum in which patients shared their experiences with each other) Follow-up care (disease monitoring, blood glucose monitoring, setting an exercise plan, dietary consultation, follow-ups by nurses on the mobile service platform)	Usual care including detailed health guidance by nurses before the discharge (counselling/ education) and a follow-up phone call after the first week and first month post-discharge (follow-up care)	The significant reduction in the results was in favour of the intervention group. • Reduction in HbA1c level – S • Reduction in the rate of hospital re-admissions – S	Good*

Abbreviations: *RCT, randomised control trial; HbA1c, glycosylated haemoglobin concentration; S, significant difference between the study groups.*

**Assessed using CONSORT score (poor ≤ 12, fair between 13 and 19, good ≥ 20 scores).*

Table 3. Studies on complex intervention (Cont.).

Author	Sample size	Design/ duration	Setting	Intervention name	Intervention components	Control group	Outcomes of interest	Quality of reporting
Zhang *et al.* 2015 (67)	327 adult patients	Cohort study 2 years	Hospital diabetes outpatient clinic providing integrated care service in Australia (Hospital & community -based settings)	An integrated model of diabetes care provided by a multi-disciplinary team comprising an endocrinologist, advanced-skilled GPs, a diabetes nurse educator, dietitian, podiatrist and psychologist	Follow-up care (assessment/screening for complications and attending weekly multidisciplinary diabetes clinic) Coordination of care (allied health available on referral depending on patient need which include services provided by a dietitian, podiatrist and psychologist) Transfer of care (reviewing and discharging patients back to their referring GP once their clinical targets are achieved or after 12 months if no further improvement can be achieved)	An assessment by a consultant endocrinologist or residents or supervised training registrars (follow-up care), and referral to a diabetes nurse educator or other allied health personnel as needed (coordination of care)	The significant reduction in diabetes-related admissions was in favour of the intervention group. **Primary outcome:** Reduction in diabetes-related hospital admissions – S **Secondary outcomes:** • Reduction in all-cause hospital admissions – NS • Reduction in non-diabetes-related hospital admissions: Intervention group had higher admissions – S	Good*

Abbreviations: *GP, general practitioner; S, significant difference between the study groups; NS, non-significant difference.*

**Assessed using TIDieR checklist (poor < 5, fair between 5 and 8, good > 8 scores).*

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